

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, September 29, 2008, 1:00 pm – 2:00 pm ET

Minutes

I. Welcome and Introductions - call participants (listed alphabetically):

- David Brown, Colgate Palmolive Company
- Iris Feliciano, Sun Pharmaceutical Industries, Inc.
- Chris Guay, The Procter & Gamble Company
- Virginia Hogan, Teva Pharmaceuticals USA
- Jeffrey Karp, Geronmed, Inc.
- Mike Koenig, U.S. Food and Drug Administration
- Carolyn Lindsay, Cardinal Health
- Andras Megyeri, Novartis Consumer Health, Inc.
- Kathryn Moreng, Bayer Consumer HealthCare
- Paulette Midgette, Johnson & Johnson•Merck Consumer Pharmaceuticals Co.
- Devon Morgan, Perrigo Company (co-leader)
- Janet Riffitts, McNeil Consumer Healthcare
- Gary Saner, Reed Technology & Information Services, Inc.
- Barbara Spallitta, Reckitt Benckiser, Inc.
- Siobhan Stevens-Miles, Merck & Co., Inc.
- Carl Strotz, Wyeth Consumer Healthcare
- Craig Trautman, Intagras
- Ann Vu, U.S. Food and Drug Administration
- Marcia Howard, CHPA staff (sub-team liaison)
- Alison Manhoff, CHPA staff

II. Standing Teleconference Date and Time

The next teleconference will be October 13, 2008, at 1:00 pm ET unless cancelled.

III. Draft Guidance

Devon Morgan (Perrigo Company; SPL OTC sub-team co-leader) and Marcia Howard (CHPA staff) explained the circumstances which resulted in the comment submission on the draft guidance to be done under the CHPA umbrella rather than the “official” SPL Working Group (SWG). This in no way affected the content of the submission and CHPA membership was not implied or expected for inclusion. Because there are FDA representatives on the Working Group and various sub-teams, any submission by the SWG must have prior approval from the SWG Leadership Team. FDA officials cannot be viewed as setting or endorsing any recommendation, provision, policy, or position outlined in submissions. Virginia Hogan (Teva Pharmaceuticals USA) noted that FDA participants function in an information-gather capacity rather than to set policy, give specific guidance, etc. Hogan, who is a member of the SWG Leadership Team (SWG LT), will get clarification about membership on the Leadership Team and under what circumstances approval is needed from the SWG LT.

Subsequent to the call, we were advised that participation on the SWG LT is open to the leaders of the various SPL sub-teams. However, the SPL Process Team (SPC) is open to anyone who is interested in sharing communications across the sub-teams. If interested in joining the SPC, please contact [Terry Brunone](#) (GlaxoSmithKline Consumer Healthcare) or [Mary Beth Wilusz](#) (Merck) who is a co-chair of the SPC. Furthermore, any submission made on behalf of the “official” SPL Working Group must be reviewed by the SWG LT and submitted under the Leadership Team’s signature.

IV. Goals and Objectives of the SPL OTC Sub-team

Based on current feedback, the primary goal of the sub-team at this time will be to develop the question-and-answer document discussed during previous calls. Sub-team members were encouraged to send questions as they arise to sub-team leaders Paula Markert (GlaxoSmithKline Consumer Healthcare) and Devon Morgan, and Marcia Howard so the document can be updated accordingly. The Q&A document will also be posted to the Wiki page.

The following questions were discussed and will be added to the Q&A

- If within an NDA there is a formulation that has different flavors, can a company enter one Content of Labeling (CoL) SPL submission with the inactive ingredients for each of the flavors or does each flavor have to have its own CoL SPL submission?

- How can companies identify potential software vendors and suppliers?

[Members should visit the SPL Wiki page at <http://spl-work-group.wikispaces.com/> for a list of vendors and suppliers who have been involved with SPL.]

It was agreed that the SPL OTC sub-team would explore hosting a separate vendor demonstration if members felt there were gaps in the vendor presentations that will be made at the upcoming DIA SPL workshop (October 29-30 in Philadelphia, PA) (see below for more information).

- Does FDA have any technical information regarding configuration of subheadings in drug facts labeling (DFL) related to the LOINC codes?
- What are the requirements for submitting the principal display panel (PDP) in SPL? Are companies required/expected to do an SPL update each time the PDP changes or is it acceptable to not list interim changes?
- How will the Jpeg images be handled within SPL and what constitutes a “representative” label?

V. Educational Opportunities

- A. DIA In-person SPL Workshop (October 29-30, 2008, in Philadelphia, PA). Please visit [CHPA website](#) for additional information, including registration materials.
- B. Generic Pharmaceuticals Association (GPhA) [Fall Technical Workshop](#) October 28, 2008, in Rockville, MD [prior to the Fall Technical Conference in Washington, DC (October 29-30)].
- C. Slides from the SPL OTC training webinar (held July 30, 2008) are available on the OTC Wiki page: <http://spl-work-group.wikispaces.com/>.

VI. Next Steps and Assignments

- A. The sub-team leaders and Marcia Howard will update the Q&A document to circulate to sub-team members for feedback.
- B. Sub-team members should email questions for the Q&A document between teleconferences so to facilitate discussion during the calls.

MDH/09-30-08

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Last Revised: September 30, 2008 Sent: September 30, 2008